REMARKS

In response to the Office Action of August 19, 2008, and the notices of non-responsive amendments of January 29, 2009 and June 11, 2009, the present application has been carefully reviewed and amended. Entry of the present amendment and reconsideration of the application are respectfully requested.

Claim Objections

Claims 1-11, and specifically Claims 1, 8 and 9, are objected to various reasons as set forth on Page 2, paragraph 1 of the Office Action mailed August 19, 2008.

Each of these claims[1] has been amended to overcome the objections.

Claim Rejection under 35 USC §112

Claim 3 is rejected under 35 USC §112 second paragraph.

Claim 3 has been cancelled, and thus this rejection is believed overcome.

Claim Rejection under 35 USC §102

Claims 8-18 stand rejected under 35 USC §102 as being anticipated by Krivitski (US Patent 5,453,576) [Paper 20080812, page 3]

[1] Claim 3 has been cancelled.

In relevant part, Krivitski '576 is relied upon to "further teach[es] details related to calibration of the sensing arrangement (column 11, lines 10-36)" [Paper 20080812, page 3]

The relied upon portions of Krivitski '576 include Figure 11:

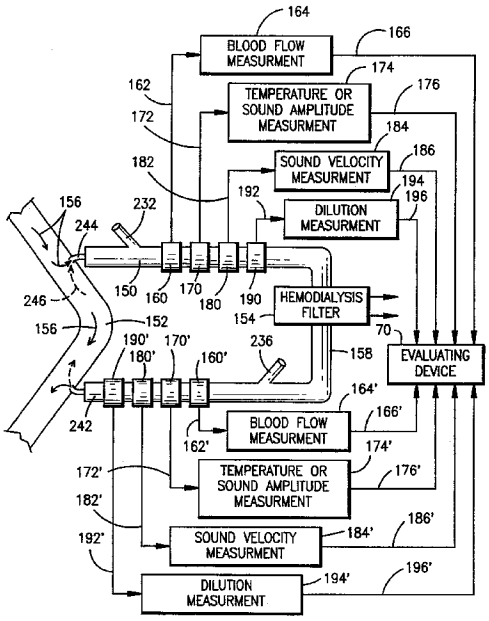

FIG. 11

As cited by the Examiner, the calibration of Krivitski '576 is:

> Another way to calibrate the perivascular sensors or the clamp-on tube sensors of FIGS. **10** and **11** is to make a calibration injection of a known indicator material directly prior to the location of the sound velocity sensor while simultaneously measuring the blood flow through the tube/vessel. A calibration injection into the arterial line, for example by way of arterial inlet ports **230** or **232** in the systems of FIGS. **10** and **11**, respectively, will change the measured sound velocity in the arterial sensors **112** or **180** as follows:
>
> $$\Delta C(t)=\Delta C_b(t)^* l_b/(l_t+l_b) \quad \text{(Eq. 12)}$$
>
> or
>
> $$S_{A.cal.isot.sound}=S_{A.b.cal.isot.sound.}{}^* l_b/(l_t+l_b) \quad \text{(Eq. 13)}$$
>
> where $S_{A.cal.isot.sound.}$ is the measured sound velocity dilution area generated by blood sound velocity dilution changes ($S_{A.b.cal.isot.sound}$). From equations 6 and 13 the average flow through the tube/vessel during the time when the indicator passes is expressed as follows:
>
> $$Q_{A.cal.}=\frac{(A_1P+2A_2P_2)\,V_{A.cal.isot.}{}^* l_b}{S_{A.cal.isot.sound}\,(l_t+l_b)} \quad \text{(Eq. 14)}$$
>
> where $Q_{A.cal.}$ is the average flow through the tube/vessel and $V_{A.cal.isot.}$ is the volume of the calibrating injection. (Col. 11)

However, this does not disclose a calibration coefficient of the sensor.

Krivitski '576 is directed to addressing the errors introduced by the vessel wall size and properties. As stated in the introduction of the portion of Krivitski '576 cited by the examiner:

> It is noted that the perivascular system of FIG. **10** cannot be precalibrated because the vessel wall size and its properties are unknown. Accordingly, the perivascular probe must be calibrated during dialysis or other treatment. (Col. 11)

The "the calibration of the sensing arrangement" relied upon by the Examiner in column 11, lines 10-36 is the measurement of a sound velocity in blood, the measured sound velocity dilution area or the average flow rate

through the tube (vessel). These do not provide a calibration coefficient of the blood property sensor.

Krivitski '576 just does not disclose the determination of a calibration coefficient of the blood property sensor. The use of the "calibration injection" in Krivitski '576 to compensate for temperature variation in the tubing material does not disclose determining a calibration coefficient of the blood property sensor.

Krivitski '576 provides a calibration for the tubing of the system.

That is, as set forth in Col. 9 and 10 of Krivitski '576,

> In the embodiments of both FIG. **10** and FIG. **11**, the ultrasonic waves of the sound sensors, such as sensors **110** and **112** in FIG. **10**, and sensors **160** and **180** in FIG. **11**, pass through the conduit, which is either the vessels **12**, **16**, or the tubing **150**,**158** as well as the blood. In such cases, the measured sound velocity is a function of the geometry of the tube/vessel and its acoustical properties, as well as the acoustical properties of the blood. The relationship between the measured sound velocity C and an unknown blood sound velocity C_b can be stated as:
>
> $$C=(C_t*l_t+C_b*l_b)/(l_t+l_b) \quad \text{(Eq. 8)}$$
>
> where C_t is the average velocity of ultrasound through the material of the tube/vessel, where l_t is the equivalent path length of ultrasound through the tube/vessel, and where l_b is the equivalent path length through the blood.

That is, as set forth in Col. 10 of Krivitski '576,

> In order to take into account the effects of the tube/vessel acoustical properties, it is necessary to calibrate the systems of FIGS. **10** and **11**. For the system of FIG. **11**, the tube system can be calibrated by filling it with a solution of known sound properties, such as a saline solution, and measuring the sound velocity. This measurement can then be compared with the velocity of sound in the blood, and the relationship between C and C_b can be found. This relationship will be valid for a constant temperature.

Krivitski '576 addresses material and geometry of tubing (or a vessel) not the calibration of a sensor.

To the extent Krivitski '576 provides for calibration, it is a calibration for the material and geometry of the tubing (or vessel), and not the sensor. Specifically,

> In such cases, the effects of the vessel or tube must be determined and then canceled out of later measurements so that the results of later blood parameter measurements will be independent of the sonic and geometric properties of the tube or the artery/vein. (Col. 3)

> In perivascular systems, however, the material and geometric characteristics of the vessel itself affect the measurements, so compensation is required, as will be described hereinbelow. (Col. 3)

> In such a case, calibration of the system is required to eliminate the effects of the tubing. As (Col. 3)

As set forth in Col. 10 of Krivitski '576:

> This makes it possible to compensate for the influence of temperature on the measured ultrasound velocity by recording the changes in the amplitude of the received sound signal ΔA(t) due to changes in temperature in accordance with the following equation:
>
> $$\Delta C_T(t)=K_T*\Delta A(t) \quad \text{(Eq. 10)}$$
>
> where K_T is a coefficient which can be calculated for the type of tubing that is used in the blood treatment system. (Col. 3)

Claims 8-11

Independent Claim 8 and dependent Claims 9-11 recite in part "determining a calibration coefficient of the blood property sensor corresponding to the measured property of the diluted blood."

There is no disclosure in Krivitski '576 of determining a calibration coefficient of the blood property sensor in the extracorporeal portion corresponding to the measured property of the diluted blood.

That Krivitski '576 provides a velocity of sound measurement, a measured sound velocity dilution area or an average flow through the tube/vessel in response to a calibration injection does not disclose "determining a calibration coefficient of the blood property sensor."

The calibration for tubing material and geometry is not calibration of a blood property sensor. As at least this limitation is absent from Krivitski '576, the outstanding rejection of Claims 8-11 has been overcome.

Claims 12-14

Independent Claim 12 and dependent Claims 13 -14 recite in part "means for determining a calibration coefficient of the blood property sensor corresponding to the detected property of the diluted blood."

As Krivitski '576 does not disclose a calibration coefficient for a blood property sensor, there is no disclosure in Krivitski '576 of "means for determining a calibration coefficient of the blood property sensor corresponding to the detected property of the diluted blood."

No portion of Krivitski '576 has been cited for the determination of a calibration coefficient of the blood property sensor or the means for the determination of a calibration coefficient of the blood property sensor.

Therefore, applicant respectfully submits Claims 12-14 are in condition for allowance.

Claim 15

Independent Claim 15 recites in part "means connected to the blood property sensor for determining a calibration coefficient of the blood property sensor corresponding to the detected property of the diluted blood in the extracorporeal portion."

Again, Krivitski '576 does not disclose the determination of a calibration coefficient of the blood property sensor, nor means connected to the blood

property sensor for determining a calibration coefficient of the blood property sensor. Therefore, Claim 15 is in condition for allowance.

Claim 16

Independent Claim 16 recites in part "determining a calibration coefficient of the blood property sensor corresponding to the measured change."

The calibration for tubing material and geometry does not disclose determining a calibration coefficient of the blood property sensor corresponding to the measured change. Further, the measurement of a sound velocity in blood, the measured sound velocity dilution area or the average flow rate through the tube (vessel) in response to a calibration injection do not provide for, or determine a calibration coefficient of a blood property sensor. Therefore, Claim 16 is in condition for allowance.

Claim 17

Independent Claim 17 recites in part "determining a calibration coefficient of the blood property sensor corresponding to the measured change."

Krivitski '576 does not disclose "determining a calibration coefficient of the blood property sensor corresponding to the measured change." Calibration for tubing for material (or geometry) does not disclose "determining a

calibration coefficient of the blood property sensor corresponding to the measured change" Therefore, Claim 17 is in condition for allowance.

Claim 18

Independent Claim 18 recites in part "determining the calibration coefficient of the blood property sensor corresponding to the measured blood property."

The use of a calibration injection [Krivitski '576, Col. 11, line 15] to measurement of a sound velocity in blood, the measured sound velocity dilution area or the average flow rate through the tube (vessel) does not provide for determining the calibration coefficient of the blood property sensor corresponding to the measured blood property. Further, the calibration of tubing material or geometry does disclose the calibration of a blood property sensor. Therefore, Claim 18 is in condition for allowance.

Claim Rejections under 35 USC §103

Claims 1-7 stand rejected under 35 USC §103 as being unpatentable over Krivitski (US Patent 5,453,576) [Paper 20080812, page 3]

Claims 1, 2 and 4-7 have been amended to recite in part "determining a calibration coefficient of the blood property sensor corresponding to the determined blood property of the diluted blood passing the blood property sensor in the venous tubing portion."

Krivitski '576 does not disclose determining a calibration coefficient of the blood property sensor. Therefore, at least this limitation is absent from the cited reference. The absence of this limitation precludes Krivitski '576 from sustaining the outstanding rejection.

Therefore, applicant respectfully submits all the pending claims, Claims 1, 2 and 4-18 are in condition for allowance, and such action is earnestly solicited. If, however, the Examiner believes that any further issues remain, the Examiner is cordially invited to call the undersigned so that any such matters can be promptly resolved.

Please grant any extensions of time required to enter this response and charge any required fees to our deposit account 03-3875.

Respectfully submitted,

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